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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,141	06/16/2000	Richard M. Lawn	99395-B	1470
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MCDONNELL BOEHNEN HULBERT & BERGHOFF			RAO, MANJUNATH N	
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CHICAGO, IL	L 60606		1652	r . /
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/596,141	LAWN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Manjunath N. Rao, Ph.D.	1652				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	36(a). In no event, however, may a reply be within the statutory minimum of thirty (30) fill apply and will expire SIX (6) MONTHS to cause the application to become ABANDO	days will be considered timely. from the mailing date of this communication. DNED (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on 11 J	<u>uly 2003</u> .					
2a) ☐ This action is FINAL . 2b) ☑ Thi	s action is non-final.	10				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
4) Claim(s) 1,2 and 6-63 is/are pending in the ap	plication.					
4a) Of the above claim(s) <u>21-55</u> is/are withdrawn from consideration.						
5)⊠ Claim(s) <u>1,8,10,12,14,16 and 18-20</u> is/are allowed.						
6)⊠ Claim(s) <u>2,6-7, 9, 11, 13,15, 17 and 56-63</u> is/are rejected.						
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Inform	mary (PTO-413) Paper No(s) nal Patent Application (PTO-152)				

- Art Unit: 1652

DETAILED ACTION

Claims 1-2, 6-63 are currently pending and are present for examination. Claims 1-2, 6-20, 56-63 are now under consideration. Claims 21-55 remain withdrawn from consideration.

Applicants' amendments and arguments filed on 7-11-03, paper No.17, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-20 of this application. Upon perusal of all the three provisional application upon which the priority dates are claimed, Examiner found that none of them provide adequate support for SEQ ID NO:3 or its fragments. None of the provisional applications disclose SEQ ID NO:3.

Applicants have not responded to the above in their response.

Specification

The disclosure is objected to because of the following informalities: The amendments to specification filed on 7-11-03, paper No.17/C are not in proper format. Furthermore, amendments requested to be made in specific pages do not match with the paragraphs or even the

Page 3

Application/Control Number: 09/596,141

Art Unit: 1652

page numbers in the specification and therefore has not been entered. Appropriate correction is required.

The amendment filed on 7-11-03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claim 62, applicants claim an isolated polynucleotide having at least 91% sequence identity with SEQ ID NO:3. Applicants have no support for the "91% sequence identity" in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Sequence compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that applicants fail to provide SEQ ID NO to sequences recited in the spec. For example see page 99. See particularly 37 CFR 1.821(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1652

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7, 62 and claims 56-59 which depend from claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6-7 and 62 recite the phrase "having ABC1 promoter activity that is at least 80% (or 91% as in claim 62) identical to ...". While Examiner has concluded that applicants are comparing sequence identity, the claim as written can also be interpreted as "polynucleotides having promoter activity that is 80% identical to polynucleotides with SEQ ID NO:3" which would not make much sense. Therefore Examiner suggests amending the claims as "...polynucleotides having ABC1 promoter activity, wherein said polynucleotides are at least 80% identical to...."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 62 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 62 is drawn to an isolated nucleic acid molecule having ABC1 promoter activity and wherein the polynucleotide is at least "91%" identical to the nucleotide sequence of any of SEQ ID NO: 3. However, a perusal of the specification indicates that applicants have no support for "91% identity" which now constitutes a "new matter". Therefore claim 62 is rejected for introducing "new matter" into the claims.

Art Unit: 1652

Claims 6-7, 56-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA comprising SEQ ID NO:3 having a promoter activity or DNA comprising specific fragments of SEQ ID NO:3 and having the promoter activity, does not reasonably provide enablement for any such DNA comprising a sequence that is 80%, 90% or 91% identical to SEQ ID NO:3 or its specific fragments (as claimed) including variants, mutants and recombinants or any DNA consisting essentially of nucleotides 1394-1532 of SEQ ID NO:3 and vectors or host cells comprising such polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 6-7, 56-63 are so broad as to encompass any polynucleotide with a promoter activity comprising DNA which is 80%, 90% or 91% identical to SEQ ID NO:3 or its specific fragments or any DNA consisting essentially of nucleotides 1394-1532 of SEQ ID NO:3 (function unknown) and vectors or host cells comprising such polynucleotides. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNA sequences that are broadly encompassed by the claims.

Art Unit: 1652

Applicants propose to use the above polynucleotides as a promoter and identify compounds that can affect that activity. However, applicants have not shown that sequences that are 80%, 90% or 91% identical to either SEQ ID NO:3 or its specific fragments or polynucleotide consisting essentially of nucleotides 1394-1532 of SEQ ID NO:3 continue to have such promoter activity. Since only the specific nucleotide sequence of SEQ ID NO:3 and its specific fragments determines the promoter activity, changing the nucleotide sequences as proposed by the applicants and/or addition of substantial amount of additional nucleotide sequence unrelated to the nucleic acid sequence of SEQ ID NO:3 may not lead to desired function of the polynucleotides. This is because the changes suggested by the applicants will result in an enormous number of nucleotide sequences that may or may not exhibit the very same promoter activity. The disclosure is limited to polynucleotides comprising only SEQ ID NO:3 or its specific fragments.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or modifications of nucleotides, as encompassed by the instant claims, and the base changes within a nucleic acid's sequence can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given DNA to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any DNA comprising SEQ ID NO:3 or its specific fragments because the specification does not establish: (A) regions of the DNA sequence which may be

Art Unit: 1652

modified without effecting the above mentioned activity/utility; (B) the general tolerance of ABC1 promoter DNA sequence to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide in SEQ ID NO:3 with an expectation of obtaining the desired biological function and utility; (D) polynucleotides consisting essentially of nucleotides 1394-1532 of SEQ ID NO:3 continue to have a promoter activity; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA comprising a polynucleotide having 80% identity to SEQ ID NO:3 or its specific fragments. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office action, applicants have traversed the above rejection arguing that the instant specification provides considerable guidance to enable a skilled artisan to make and use a polynucleotide having promoter activity that is at least 80% identical to SEQ ID NO:3 or its specific fragments. Applicants argue exhaustively as how the specification teaches methods of producing the polynucleotides chemically, enzymatically or metabolically etc. and methods of making variants by substitutions deletion or additions or due to degeneracy and

Art Unit: 1652

recombinant techniques to produce exemplary polynucleotides etc. Applicants also argue that the specification provides assays to test the polynucleotides for promoter activity. Applicants also refer to pages 27 and 39 for support on this matter. Examiner respectfully disagrees with such an argument as being persuasive to overcome the above rejection. This is because first of all a perusal of pages 27 and 39 does not provide support for modification of SEQ ID NO:3 in particular. All the information on those two pages are generalized information and more so referring to polypeptides. The specification is silent on the important part of the enabling homologous sequences. The specification is silent to those skilled in the art as to the regions on SEQ ID NO:3 where changes can be made while preserving the function of the polynucleotide as a promoter. Contrary to Examiner's allegation, applicants submit that it is routine experimentation to screen variant polynucleotides for promoter activity using the well known techniques. Applicants also argue that the law clearly states that "a considerable amount of experimentation is permissible, if it is routine" and that the actual experimentation even if complex does not necessarily make it undue. This is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in

Page 9

Application/Control Number: 09/596,141

Art Unit: 1652

which the experimentation should proceed. Such guidance has not been provided in the instant specification. Applicants also argue that contrary to Office's allegation, the specification establishes regions of the polynucleotide sequence that cannot be modified without affecting activity by teaching the positions of regulatory elements such as the TATA box, transcription factor binding sites etc. While this may be so, such information, which are the hall marks of a promoter sequence would be well known to those skilled in the art. The identification of TATA box or transcription binding regions are well known to those skilled in the art and it is also well known in the art that modifying such essential region would nullify or affect the promoter activity in a negative fashion. Therefore the above argument is also not persuasive to overcome the rejection. Finally applicants argue that the specification establishes that nucleotides 1394-643 retains promoter activity and based on this information, the sites mapped and disclosed in SEQ ID NO:3 as well as other known and published consensus sequences one skilled in the art would realize which areas and sequences of the promoter region could be modified without abolishing the promoter activity. Examiner respectfully disagrees with such an argument and reiterates that unless applicants teach (A) regions of the DNA sequence which may be modified without effecting the above mentioned activity/utility; (B) the general tolerance of ABC1 promoter DNA sequence to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide in SEQ ID NO:3 with an expectation of obtaining the desired biological function and utility; (D) polynucleotides consisting essentially of nucleotides 1394-1532 of SEQ ID NO:3 continue to have a promoter activity; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible

Art Unit: 1652

choices is likely to be successful, above claims remain non-enabled. Therefore the above rejection is maintained.

After considering the amendments to claims 1-20 (i.e., providing the function of the claimed polynucleotides), Examiner has withdrawn the previous rejection of claims 1-20 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification. However, the same rejection is maintained on new claims 60-61 (see below).

Claims 60-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules consisting essentially of (interpreted as "comprising" in biotechnology arts) nucleotides 1394-1532 of SEQ ID NO:3.

The specification does not contain any disclosure of the function of all DNA sequences that are encompassed by the claims. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification does not disclose even a representative number of species of the claimed genus with specific function which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Art Unit: 1652

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

After considering the amendments and applicant's arguments, Examiner has withdrawn all previous rejections under 35 U.S.C. 102. Therefore all arguments against those rejections are moot. However, new rejection are now maintained as indicated below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 9, 11, 13, 15, 17, 63 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Tall et al. (WO 200183506-A1, 11-8-01). This rejection is based upon the public availability of a printed publication. Claims 2, 9, 11, 13, 15, 17, 63 of the instant application are drawn to isolated polynucleotide having ABC1 promoter activity and comprising nucleotides 1181-1643 of SEQ ID NO:3 or isolated polynucleotide having ABC1 promoter activity and comprising a nucleotide sequence that is at least 90% identical to nucleotides 1181-1643 of SEQ ID NO:3

Art Unit: 1652

(claim 63), vectors and host cells comprising the same. Tall et al. (see enclosed sequence alignment as well) disclose an identical polynucleotide having ABC1 promoter activity and comprising nucleotides 1181-1643 of SEQ ID NO:3, composition comprising the same, vectors and host cells comprising the same. Therefore, Tall et al. anticipate claims 2, 9, 11, 13, 15, 17, 63 as written. (Note: Examiner has not given the benefit of US provisional priority dates and for purposes of the above rejection, Examiner has considered the effective filing date 6-16-2000).

Claims 60-61 are rejected under 35 U.S.C. 102(a) as being anticipated by Birren et al. (GenEmbl Database accession No. AC012230, 4-22-2000). This rejection is based upon the public availability of a printed publication. Claims 60-61 of the instant application are drawn to isolated polynucleotide consisting essentially of (comprising of) nucleotides 1394-1532 of SEQ ID NO:3, and vectors comprising the same. Birren et al. disclose an identical polynucleotide consisting essentially of (comprising of) nucleotides 1394-1532 of SEQ ID NO:3, and vectors comprising the same. Therefore, Birren et al. anticipate claims 60-61 as written. (Note: Examiner has not given the benefit of US provisional priority dates and for purposes of the above rejection, Examiner has considered the effective filing date 6-16-2000).

Claims 6, 56, 58 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Rosier-Montus et al. (US 2002/0146792-A1, US Priority 5-2-2000). This rejection is based upon the public availability of a printed publication. Claims 6, 56 and 58 of the instant application are drawn to isolated polynucleotide having ABC1 promoter activity wherein said polynucleotide is at least 80% identical to SEQ ID NO:3 isolated polynucleotides comprising such polynucleotides

Art Unit: 1652

and vectors comprising said polynucleotides. Rosier-Montus et al. disclose an identical polynucleotide having ABC1 promoter activity wherein said polynucleotide is more than 80% identical (see enclosed sequence alignment) to SEQ ID NO:3 and polynucleotides comprising such more than 80% polynucleotides including vectors. Therefore, Rosier-Montus et al. anticipate claims 6, 56 and 58 as written. (Note: Examiner has not given the benefit of US provisional priority dates and for purposes of the above rejection, Examiner has considered the effective filing date 6-16-2000).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 57, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosier-Montus et al. (US 2002/0146792-A1, US Priority 5-2-2000). Claims 7, 57, 59 in this instant application are drawn to isolated polynucleotide having ABC1 promoter activity wherein said polynucleotides are at least 80% identical to specific fragments of SEQ ID NO:3 and vectors comprising the same. (Note: Examiner has not given the benefit of US provisional priority dates and for purposes of the above rejection, Examiner has considered the effective filing date 6-16-2000).

Rosier-Montus et al. teach a polynucleotide capable of regulating the transcription of ABC1 gene which is a causal gene for pathologies linked to dysfunction of cholesterol

Art Unit: 1652

metabolism. The reference actually teaches a polynucleotide with such an activity wherein the polynucleotide is 90.4% identical to SEQ ID NO:3 (see enclosed sequence alignment). The invention also relates to nucleotide constructs comprising a polynucleotide encoding a polypeptide placed under the control of said regulatory sequence derived from ABC1 promoter sequence, including vectors and host cells as well as method of screening molecules which are capable of modifying the activity of the regulatory sequence with ABC1 promoter activity. However, the reference does not specifically teach the fragments of regulatory ABC1 polynucleotides that are as claimed in claim 7.

Using the teachings of above the reference, it would have been obvious to those skilled in the art to conduct deletion experiments in order to identify essential and non-essential portions of the sequences and come up with specific fragments which retain the specific ABC1 promoter activity. One of ordinary skill in the art would have been able to do this as the art is rich in methods to identify promoter activity related sequences. One of ordinary skill in the art would have been motivated to do so in order to generate the minimum length of polynucleotide sequence with said properties so that it can be incorporated in to vector constructs and used for screening compounds that modulate the activity of the promoter. One of ordinary skill in the art would have been further motivated to do so as Rosier-Montus et al. teach that this gene is a causal gene for pathologies linked to dysfunction of cholesterol metabolism. One of ordinary skill in the art would have a reasonable expectation of success as the above reference teaches an almost identical polynucleotide as in the instant invention with almost identical goals for its use.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

Art Unit: 1652

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Claims 1, 8, 10, 12, 14, 16, 18-20 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

Manjunath N. Rao October 3, 2003